UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,871	12/11/2003	Dennis Robert Conlon	INL-071	8081

22832 7590 09/24/2007

Kirkpatrick & Lockhart Preston Gates Ellis LLP
(FORMERLY KIRKPATRICK & LOCKHART NICHOLSON GRAHAM)
STATE STREET FINANCIAL CENTER
One Lincoln Street
BOSTON, MA 02111-2950

EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	

MAIL DATE	DELIVERY MODE
09/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,871	CONLON ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication:
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/11/03, 9/1/04, 7/20/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Part b) of claim 27 is indefinite since it is not clear what type of "signal" is obtained. Does this signal represent the conductivity of the reference solution? See this same problem with the "signal" obtained in part d) of claim 28. In part c) of claim 27, the phrase "the reference solution conductivity" lacks antecedent basis.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Chait et al (US 6,136,960).

Chait et al teach of a two-phase composition comprising polyethylene glycol and dextran in a sodium/potassium phosphate buffer. See lines 35-42 in column 3 and lines 13-28 in column

6 of Chait et al. The composition disclosed by Chait et al would inherently have a conductivity when measured with an appropriate instrument, and this conductivity would naturally correspond to some known hematocrit level, whether it be normal or abnormal.

5. Claims 1-6, 8-11 and 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryan (US 5,849,517).

Ryan teaches of a composition used for fixing and stabilizing tissues and cells. The composition comprises an active agent in a solution. The active agent is diazolidinyl urea in a buffered physiological salt solution. The composition also preferably comprises an alcohol solvent and polyethylene glycol. The alcohol solvent can be ethylene glycol, propylene glycol or glycerol. Additional components may also be present in the composition such as mordants, buffers, and osmotically active substances. Examples of suitable mordants include ions such as calcium. Examples of suitable osmotically active substances include sugars such as polysaccharides. The composition is used to stabilize cells in blood samples. See lines 1-30 in column 4 and lines 6-65 in column 7 of Ryan. Therefore, the composition taught by Ryan can include a water-soluble polymer in the form of polyethylene glycol, a glycol compound as an alcohol solvent, a polysaccharide, and an analyte ion such as calcium. The composition disclosed by Ryan would inherently have a conductivity when measured with an appropriate instrument, and this conductivity would naturally correspond to some known hematocrit level, whether it be normal or abnormal.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 7 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan (US 5,849,517). For a teaching of Ryan, see previous paragraphs in this Office action.

Ryan fails to teach that the polysaccharide included in the composition as an osmotically active substance can be dextran. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use dextran as the polysaccharide osmotically active substance in the composition taught by Ryan since dextran is a very well-known polysaccharide material that is compatible with biological fluids, such as the blood fluids being preserved with the composition taught by Ryan.

9. Claims 1-5, 8-11, 15-22 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al (US 4,686,479, submitted in the Information Disclosure Statement filed on December 11, 2003).

Young et al teach of an apparatus for determining the hematocrit level of blood and a method for calibrating the apparatus. The hematocrit level of a blood sample is measured by flowing a sample of blood along a liquid flow path in the apparatus, and using electrodes in the flow path to obtain electrical signals representative of the sample's electrical conductivity, and

the concentration of an ion species in the sample. A control solution of the ion species at a known concentration is used for evaluating the hematocrit detection apparatus. The control solution has a conductivity measurement corresponding to a known equivalent hematocrit level. The control solution comprises an analyte ion such as sodium ion, and an ion activity coefficient enhancer in an aqueous, buffered solution. The ion activity enhancer serves to increase the ion activity measured by the sodium ion-sensing electrode and to increase the resistance measured by the hematocrit resistance detector. By including such an enhancer in the control solution, the actual sodium ion concentration may remain below physiological levels, but the signal provided by the sodium ion-sensing electrode will be equivalent to a physiological sodium ion concentration. Young et al teach that suitable activity coefficient enhancers include polar, water miscible organic compounds, particularly polyols such as polyethylene glycol, glycerol and polypropylene glycol. It is possible using such activity enhancers to formulate control solutions with sodium ion concentrations in the normal range and with conductivities characteristic of a sample having a normal hematocrit level. Young et al also teach that the control solution can have known levels of oxygen and carbon dioxide therein to serve as a gas standard representing physiological levels. Young et al teach that the control solution is used to calibrate an apparatus used for measuring both analyte ion concentrations and hematocrit in biological samples by introducing the control solution into the apparatus, obtaining signals from the apparatus corresponding to both the ion concentration level and hematocrit of the control solution, and adjusting the apparatus so that the signals obtained are representative of the conductivity and ion concentration of the control solution. See the abstract, lines 22-36 in column 3, lines 14-68 in column 11 and lines 1-52 in column 12 of Young et al.

Young et al fail to specifically teach that the control solution contains more than one of the ion activity enhancers therein. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include more than one of the ion activity enhancers, such as both polyethylene glycol and glycerol, into the control solution taught by Young et al since it would flow logically that the combination would produce the same effect, and the individual enhancers would supplement each other.

10. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al (US 4,686,479) in view of the Nova Biomedical Corp. Product Information Insert (reference C1 in the Information Disclosure Statement filed on December 11, 2003). For a teaching of Young et al, see previous paragraphs in this Office action. Young et al fail to teach that the control solution used for calibrating a hematocrit measuring device includes therein a biological metabolite such as glucose, lactate, etc.

The Nova Biomedical Corp. Product Information Insert teaches of a control material used to calibrate instruments that measure pH, pCO2, pO2, oxygen saturation, hematocrit, hemoglobin, sodium, potassium, chloride, calcium, glucose and lactate in biological samples. The control material comprises known levels of sodium, potassium, chloride, calcium, glucose and lactate. In addition, the control material is equilibrated with known levels of oxygen and carbon dioxide. The control material produces a conductivity signal that is equivalent to a known hematocrit level in whole blood. See the entire Nova Biomedical Corp. Product Information Insert.

Based upon the combination of Young et al and the Nova Biomedical Corp. Product Information Insert, it would have been obvious to one of ordinary skill in the art to include in the

control solution taught by Young et al a biological metabolite such as glucose or lactate since the Nova Biomedical Corp. Product Information Insert teaches that control materials used to calibrate instruments that measure hematocrit using a conductivity signal advantageously include therein biological metabolites such as glucose and lactate since these metabolites are routinely measured in blood samples along with hematocrit on an automatic instrument, such as the one calibrated using the control solution of Young et al.

11. Claims 6-7 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al in view of Mast (US 3,920,580). For a teaching of Young et al, see previous paragraphs in this Office action. Young et al fails to teach that a polysaccharide such as dextran is contained within the control solution for calibrating a hematocrit instrument.

Mast teaches of a liquid control solution that includes therein antidiffusing agents such as the polysaccharide dextran. Mast teaches that dextran in a liquid control material serves to modify both the viscosity and osmotic pressure of the control solution. See lines 5-29 in column 2 of Mast.

Based upon the combination of Young et al and Mast, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include dextran in the hematocrit control solution taught by Young et al so as to provide a means to control both the viscosity and osmotic pressure of the control solution, in accordance with the teaching of Mast.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Guirguis et al, who teach of a composition containing ethylene glycol, polyethylene glycol and dextrose; Ryan (US 6,337,189) who teaches of a composition

containing polyethylene glycol and a polysaccharide; and Buhl et al who teach of a composition containing dextran and polyethylene glycol.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

September 7, 2007

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700